# EXHIBIT E

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# IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LIGITATION

Master File No. 2:12-MD-02327 MDL No. 2327

THIS DOCUMENT RELATES TO PLAINTIFF:

JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

Diane Bellew (2:12-cy-22473)

# RULE 26 EXPERT REPORT OF HOWARD JORDI, PhD

# I. Background and Qualifications

I. Dr. Howard Jordi received my undergraduate degree in Chemistry from Northern Illinois University in 1967 and my Ph.D. in biochemistry from the same university in 1974.

From 1973-1977. I served in the United States Army Institute of Dental Research where I characterized various drugs contained in biodegradable copolymers of polylactic and polyglycolic acid. I then worked at Water's Associates from 1977-1980. Water's is a world leader in the sale of a wide range of analytical technologies including liquid chromatography. mass spectrometry, rheometry and microcalorimetry. At Waters, I progressed from a Biological Applications chemist to the laboratory manager for the life science division and finally to the Chemicals Applications Manager for the Chromatography Supplies Division.

I am the founder of Jordi Labs and served as president and CEO from 1980-2008. Jordi Labs was founded to provide high quality analytical services to the polymer and plastics industries. In my role as President and CEO, I developed hundreds of analytical methods and have analyzed all of the major polymer systems (polypropylene, polyethylene, urethanes, styrenics, etc.). In this capacity, I have been analyzing polypropylenes for over 25 years. I have deformulated numerous polypropylene samples including identifying and quantifying their additive packages and have been aiding clients for over 25 years in the identification of the root cause of failure in polypropylene systems. I have served extensively as a consultant on polymer related failures for a wide range of industrial clients and have over 40 years of practical experience in the analytical chemistry of polymers. I have in-depth knowledge of a wide range of analytical techniques including FTIR, NMR, DSC, TGA, HPLC, SEM, GPC, DMS, LCMS, GCMS, nanothermal analysis, H-GCMS and PYMS among others. Jordi Labs currently offers over 20 different analytical techniques. I have developed a range of polymeric chromatography columns for polymer molecular weight determination, some of which are patented.

Just like the Prolift device that was implanted in Ms. Bellew, the TVT and TVT-O devices analyzed from 24 other patients' explants are manufactured using Prolene polypropylene, with the only difference being the fiber size and amount of Prolene used to manufacture the different devices. According to Ethicon documents, the mesh material in the TVT & TVT-O products is Prolene Old Construction 6 mil mesh. 102,103,104 While Prolift is manufactured with a smaller fiber diameter, 105 it is still made with the same Prolene polypropylene material used to manufacture the TVT and TVT-O devices.

The 24 explant samples analyzed by Jordi Labs were selected randomly at Steelgate, the facility which was storing the explants after they were surgically removed by the patients' physicians. Only TVT and TVT-O explants were selected. The protocol further required that only explants with sufficient material for histopathology and degradation analysis would be used. The patients' medical records, including prior pathology reports, were not considered in the selection process.

# A. Sample Identification

## Control Samples - TVT and TVT-O

#### Jordi Number/Lot Number

- 3. 13158 Lot 3436364
- 4. 13159 Lot 3405405
- 5. 13160 Lot 3405460
- 6. 13161 Lot 3422128
- 7. 13162 Lot 3398135
- 8. 13163 Lot 3405474

#### **Explant Samples**

# Jordi Number/Patient Name

- 1. 13400 Oiler, Jennell
- 2. 13401 Simpson, Cynthia Ann
- 3. 13402 Valentino, Gloria
- 4. 13403 Herman, Sheryl
- 5. 13404 Phillips, Amy Nicole
- 6. 13405 Smith, Eva
- 7. 13406 Wilson, Virginia
- 8. 13407 Dowden, Ann Marie
- 9. 13408 Johnston Williams, Shari
- 10. 13409 Sharp, Jaqueline D.
- 11. 13410 Ioannov, Stella

<sup>&</sup>lt;sup>102</sup> ETH.MESH.02219202 - Material Specification for TVT Prolene Polypropylene Mesh Roll Stock

ETH.MESH.09479067 - TVT PROLENE Polypropylene Mesh Rool Stock Appendix II Digital Photograph of 050166

ETH.MESH.01816988 – Mesh Timeline

<sup>105</sup> ETH.MESH.01816988 – Mesh Timeline

### XIII. COMPENSATION

I am compensated for investigation, study and consultation in this case at the rate of \$350.00 per hour.

This 7th day of July. 2014

Howard Jordi, Ph.D.

Howard Jouls